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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,555	10/15/2001	Barry J. Marshall	BAL-99A (16843)	1969
7590 11/05/2004			EXAMINER	
Timothy A. Cassidy Dority & Manning, Attorneys at Law, P.A. P.O. Box 1449 Greenville, SC 29602			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/977,555	<b>Applicant(s)</b> MARSHALL ET AL.5	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The amendment received 10/21/04 has been received and claims 1-12, 14-16, 18-22 are currently pending in this application. The claims as submitted in the amendment are inconsistent with the claims previously submitted, a corrected copy of all pending claims is requested. For example, in claim 14 and all occurrences, the claims now recite "being capable of" which was not in the previous version of the claims and remains improper. All related issues under 35 USC 112 will be considered after receipt of a complete accurate set of claims to avoid confusion.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 8, 9, 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothgang.

Rothgang (EP 0 369 292 A1) entitled "Diagnostic Metering Unit for Urease Determination" teaches in the English translation provided on page 5 lines 9-11, the composition components may be provided as a powder. On page 7 line 1, phenol red is shown as an indicator. On page 7 first paragraph, the indicator may be separate from other components. On page 9 last line bridging to page 10, the pH indicator can be located apart from the other components.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 5, 7, 12, 14-16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rothgang in view of King.

Rothgang (EP 0 369 292 A1) entitled "Diagnostic Metering Unit for Urease Determination" teaches in the English translation provided on page 5 lines 9-11, the composition components may be provided as a powder. On page 7 line 1, phenol red is shown as an indicator. On page 7 first paragraph, the indicator may be separate from other components. On page 9 last line bridging to page 10, the pH indicator can be located apart from the other components.

The claims differ from Rothgang in that they include the limitations of the second (indicator) composition comprises a gel and specified particle sizes of urea.

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King (5,498,528) entitled "Detection of H. pylori" teaches in column 4 gastric biopsy specimens and medium is a semisolid. Also, pH indicators may be employed in a semisolid form. In column 9 first paragraph, gels are shown including agar.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ the method of Rothgang with an indicator composition in a gel as shown by King because King shows indicator compositions in gel form for the same function as presently claimed. The indicator compositions of Rothgang are in solution. To employ the same indicator solutions of Rothgang in a gel form for their known function with the expected result would have been obvious. Regarding particle sizes of urea, no function is attributed to the particle size and it would appear to be a mere design choice.

Applicant's arguments filed 10/21/04 have been fully considered but they are not persuasive.

The present specification teaches the point of novelty resides in the urea is in a dry powdered form and the sample is contacted directly with the dry powder. Applicants argue that Rothgang does not teach nor fairly suggest the sample is directly contacted with a dry powdered urea.

It is the examiner's position that this feature is not presently claimed. Present claims 1 and 18 are written in open-ended comprising terminology where the sample is contacted with a powdered composition but does not exclude the addition of water as is

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taught by Rothgang. Claim 14 simply states the sample is contacted with urea. None of the claims state the sample is contacted directly with dry powdered urea.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Castoms

Ralph Gitomer  
Primary Examiner  
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